



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 12 2002

Dear Colleague:

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (PDUFA III). Among other things, this law authorizes the Food and Drug Administration (FDA) to continue to collect three types of user fees from applicants who submit certain new drug and biological product applications and supplements and for certain products and establishments. FDA was first authorized to collect user fees through September 30, 1997, under the Prescription Drug User Fee Act of 1992 (PDUFA I). The Food and Drug Administration Modernization Act of 1997, which included Subtitle A — Fees Relating to Drugs (PDUFA II), authorized FDA to collect fees for an additional 5 years, through September 30, 2002. PDUFA III extends FDA's authority to collect fees for 5 more years, through September 30, 2007, and includes a number of technical revisions that affect the way certain fees are assessed and collected.

The purpose of this letter is to alert you to some of the technical revisions to the Federal Food, Drug, and Cosmetic Act (the Act) and to request your prompt assistance in providing the additional information necessary under PDUFA III to accurately prepare the fiscal year (FY) 2003 invoices for product and establishment fees.

**I. What Are the Technical Revisions to the Act?**

The changes described below affect the way product and establishment fees will be assessed for FY 2003.

**A. When are annual product and establishment fees due?**

Unlike PDUFA I and PDUFA II,<sup>1</sup> annual product and establishment fees for PDUFA III are due on October 1 each year,<sup>2</sup> so that FDA no longer needs to carry forward large cash surpluses from year to year. FDA will also have access to revenue as early in FY 2003 as invoices can be issued

<sup>1</sup> Under PDUFA I and PDUFA II, annual product and establishment fees were due on January 31 of each year.

<sup>2</sup> Section 736(a)(2)(A) of the Act as amended by the Prescription Drug User Fee Amendments of 2002.

and fees collected, rather than waiting until January 31 to collect funds. We expect to send out invoices for FY 2003 in August of this year.<sup>3</sup>

## **B. How will product fees be assessed under PDUFA III?**

### **1. For Drug Products**

Under PDUFA III, the term "prescription drug product" has been modified to use the *Prescription Drug Product List in the Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book) (the active portion) as the basis for identifying which products are considered prescription drug products for fee assessment purposes. Products identified in the Orange Book Prescription Drug Product List with no generic competition will be assessed a fee regardless of drug listing status. Those products in the Orange Book with generic competition will not be assessed a fee. Under PDUFA I and PDUFA II, any prescription drug product (including a licensed biological) approved and eligible for drug listing not subject to generic competition was subject to user fees.

### **2. For Biological Products**

In addition to the Orange Book technical change to the Act, PDUFA III includes the addition of the reference to a list of products approved under human drug applications under section 351 of the Public Health Service Act created and maintained by the Secretary. Because biologics approved under section 351 of the Public Health Service Act are not listed in the Orange Book, a separate listing of licensed products which are user fee liable will be maintained. All non-revoked biological products meeting the definition of human drug products will be included in the billable biologics list. Please note that the products on the list are subject to user fee regardless of whether they are currently being manufactured or not. This refers to the current FDA method of identifying biological products considered to be prescription drug products for fee assessment purposes.

### **3. Drug Listing**

The drug listing criterion<sup>4</sup> for assessing product fees is omitted in PDUFA III. Determining eligibility for listing is administratively complex and sometimes resource intensive, in part because the drug listing process under section 510 of the Act is often controlled by a repacker or distributor, rather than the sponsor of a product.

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<sup>3</sup> Prescription Drug user Fee Rates for FY 2003 will be calculated and published in a Federal Register notice in August 2002.

<sup>4</sup> Section 736(a)(3)(i) of the Act under PDUFA I and PDUFA II.

For example, the sponsor may not be distributing the drug product; however, if the drug product is listed under section 510 of the Act by anyone, including a repacker or distributor, then the sponsor was still responsible for paying a product fee. Many sponsors had a difficult time convincing repackers and distributors to delist their drug product appropriately and in a timely fashion. Additionally, biologics manufacturers often were not clear on the requirement to list their biologic products.

The Orange Book and billable biologics list criterion<sup>5</sup> provides sponsors with control of their list of billed products and should provide an easier way to remove products from the billing list. Sponsors can review what the product portion of their annual bill will look like by monitoring the Orange Book or billable biologics list on the Internet.<sup>6</sup>

### **C. Are There Other Changes to the Act Relating to User Fees?**

Yes. For other changes to the Act relating to prescription drug user fees, please refer to the attached document (Attachment D) which was excerpted from the House of Representatives Conference Report 107-481 to Accompany H.R. 3448 — Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The excerpt includes Title V — Additional Provisions, Subtitle A — Prescription Drug User Fees, and Subtitle B — Additional Authorizations of Appropriations Regarding Food and Drug Administration.

## **II. What Else Is Attached to This Letter?**

We have enclosed a list of product and establishments for which you were assessed fees in FY 2002 (Attachment B). The list contains all products and establishments that appeared on invoices issued in January 2002. We have also attached a list of all the products for which you are listed as the sponsor in the active portion of the Orange Book (Attachment C). If we were to issue the FY 2003 bill today, this second list would indicate how the product portion of your new bill would appear. These two lists may differ.

## **III. What Does FDA Need to Ensure an Accurate Bill for FY 2003?**

To ensure that the August invoices accurately assess FY 2003 product and establishment fees under PDUFA III, we are asking for your assistance in providing the following information:

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<sup>5</sup> Section 736(a)(3) of the Act as amended by the Prescription Drug User Fee Amendments of 2002.

<sup>6</sup> The Orange Book is accessible at [www.fda.gov/cder/orange/default.htm](http://www.fda.gov/cder/orange/default.htm). The biologics listing will be available in August 2002 at: [www.fda.gov/cber/products.htm](http://www.fda.gov/cber/products.htm).

**A. Product Lists (Attachment B and Attachment C)**

Please revise the list of products as follows:

- Note on the lists any products submitted under section 505(b)(2) of the Act.
- Note on the list any products that have generic competition.
- Mark on the list any products that are large volume parenteral (LVP) **DRUG** products (under PDUFA III DRUG LVPs are not assessed a product fee). **BIOLOGICAL** products intended for single dose injection for intravenous use or infusion are still fee liable. You should not delete them from the list.
- Add any approved product not on the list that you believe should be assessed a fee (e.g., new approval). Please include the reason why you believe it should be assessed a fee.
- Please contact the Orange Book Staff, HFD-093 with any corrections to the Orange Book. For example, if you are no longer marketing your drug product and you have delisted it under section 510 of the Act, you should alert the Orange Book Staff, so that the drug product can be moved to the discontinued portion of the Orange Book. Conversely, if you are marketing your drug product and it is in the discontinued portion of the Orange Book, you should also notify the Orange Book Staff.

In order for the Agency to make all the necessary changes to the Orange Book and issue invoices in August, you must notify the Orange Book Staff by close of business July 1, 2002. Please note this information on the product list as well.

You can contact the Orange Book staff by e-mail:

[DRUGPRODUCTS@CDER.FDA.GOV](mailto:DRUGPRODUCTS@CDER.FDA.GOV)

Note:  
Address and Fax  
number are outdated  
for the Orange Book.

See 2003 Letter for  
updated contact  
information.

You can send them information by facsimile at 301-594-6463. If you wish to send a paper copy confirming the faxed or e-mailed information you can mail it to:

FDA/CDER Orange Book Staff, HFD-093  
5600 Fishers Lane  
Rockville, Maryland 20857

If you wish to send it using an overnight courier service (e.g., FedEx, DHL) you can send it to:

FDA/CDER Orange Book Staff, HFD-093

Park Building, Suite 3-22  
12420 Parklawn Drive  
Rockville, Maryland 20857

- For licensed biologics, please contact the Regulatory Information Staff, 301-827-3503 about any questions or discrepancies.

#### **B. Establishment List**

Please revise the list of establishments as follows:

- Add to the list of establishments the name, site address, and CFN number (if known) of all approved manufacturing sites (not the corporate headquarters address) engaged in the manufacture of final dosage forms of any of your prescription drug products on the updated Orange Book product list. Include establishments owned by contract manufacturers. Do not include establishments that function solely as packagers or that do not make final dosage forms.
- Delete any establishments from the list that do not manufacture any prescription drug products in final dosage form. Please include a brief statement of the reason for deletion (for example, state the operation performed at the establishment to be deleted). If an establishment owned by your firm is not associated with the production of any of your products, but contracts to make products for another firm, please indicate that the facility serves as a contract manufacturer only.

#### **C. Matching the Product List with the Corresponding Establishment**

For each product on the list, please indicate the establishment or establishments where the final dosage form of the product is produced. We suggest numbering the establishments after all the additions and deletions have been made and writing the number or numbers you assigned to each establishment next to each product produced in final dosage form at that establishment.

#### **D. Contact Information**

Finally, update the Attachment A information with the appropriate name, address, title, phone, and fax number of your company contact for user fee purposes. Keep in mind that all correspondence regarding user fees will be addressed to this contact name.

Please return the information by facsimile (301-827-5562) to Michael Jones. If you wish to send a paper copy confirming the faxed information, you can mail it to:

Michael Jones  
Special Assistant  
Office of Regulatory Policy, HFD-5  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If you wish to send it using an overnight courier service (e.g., FedEx, DHL) you can send it to:

Michael Jones  
Special Assistant  
Office of Regulatory Policy, HFD-5  
Center for Drug Evaluation and Research  
Food and Drug Administration  
1451 Rockville Pike,  
Rockville, Maryland 20852

We apologize for the short notice for this request but we believe that much time *and effort will be saved by ensuring that the information from which the FY 2003 invoices are generated is accurate and up-to-date.* To allow time for us to process the information you provide, we are requesting that you respond by close of business Monday, July 1, 2002. If you have any questions, please call Michael Jones, Beverly Friedman, or Tawni Schwerner at 301-594-2041.

Your assistance is greatly appreciated. FDA is committed to continue working jointly with industry to ensure the continued success of this program.

Sincerely yours,

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Helen S. Horn, Acting Director  
Office of Financial Management

Attachment A – Contact Information  
Attachment B – January 2002 Invoice  
Attachment C – Proposed FY 2003 Product List  
Attachment D – Excerpt from Conference Report

# Attachment A

Our files show the contact person, address, and telephone number below for all correspondence, invoices, and inquiries for your firm pertaining to user fees under the PDUFA. Please make corrections below. Please confirm that the information presented is correct and sign, date, and return this page to us.

Name of Firm:

Address of Firm

Attention:

Title:

Phone:

Facsimile:

Changes are needed.

No changes.

TAX ID Number:

Signature:

Title:

Date:

## ATTACHMENT B

Attachment B is our list of your firm's products and establishments that were subject to fees under the PDUFA as amended by the Modernization Act as of December 2001.

**Please sign, date, and return Attachments B and C by July 1, 2002.**

\_\_\_\_\_ The information in Attachments B and C is complete and correct as revised for the assessment of product and establishment fees under PDUFA III. All information requested in the letter has been included.

**Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Firm:** \_\_\_\_\_

**ATTACHMENT C – PROPOSED FY 2003 PRODUCT LIST**

Attachment D

Excerpted from the House of Representatives Report 107-481, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Conference Report to Accompany H.R. 3448, May 21, 2002

TITLE V – ADDITIONAL PROVISIONS

The Managers agree to the following provisions.

SUBTITLE A – PRESCRIPTION DRUG USER FEES

*Section 501. Short Title*

Designates the name of this title as the "Prescription Drug User Fee Amendments of 2002."

*Section 502. Findings*

Declares the findings of Congress related to the reauthorization of prescription drug user fees.

*Section 503. Definitions*

The following terms in section 735 of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) (21 U.S.C. 379g) are modified by this section: human drug application, prescription drug product, process for the review of human drug applications, and adjustment factor. These modifications are necessary to give effect to the changes instituted by the reauthorization of the Prescription Drug User Fee Act (PDUFA).

The term "human drug application" is modified to make a technical correction.

The term "prescription drug product" is modified to allow the Secretary to use the *Prescription Drug Product List* (the active portion) in the "Approved Drug Products with Therapeutic Equivalence Evaluations," (the Orange Book) as the basis for identifying which products should be considered to be prescription drug products for fee assessment purposes. The Managers expect that these proposed changes will lead to a more efficient, less burdensome, billing procedure. Under current law, any prescription drug product eligible for drug listing is subject to product fees. Determining eligibility for listing is administratively complex and sometimes resource intensive. In addition, listing is often controlled by a re-packer or distributor rather than by the sponsor, but the sponsor must nonetheless pay the product fee. The Managers expect that the use of the Orange Book, which is found on FDA's Internet site, as the basis to identify products for user fee assessment purposes will not be construed to affect the legal status of the book or the products in the book. The purpose of using this method is merely a tool for the Secretary to provide a public, efficient billing process. It also provides sponsors an easier way to remove products from the list that is the basis for billing.

Also, the addition of the reference to the list of products approved under human drug applications under section 351 of the Public Health Service Act created and maintained by the Secretary refers to the current FDA method of identifying biological products considered to be prescription drug products for fee assessment determinations. The Managers do not intend this to be a change in practice; rather it documents FDA's current practice. The list is to be provided on FDA's Internet site.

A further change to the term "prescription drug product" deletes the clause "does not include a large volume parenteral drug product approved before September 1, 1992." As a result, any large volume parenteral (LVP) product is treated as a prescription drug product and is subject to a fee. However, when coupled with a corresponding change proposed to section 736(a)(3)(B), all LVP's would be exempt from product fees in this reauthorization, including products approved after September 1, 1992. The Managers intend this change to decrease FDA's administrative burden in determining which products should be billed.

The term "process for the review of human drug applications" is modified to allow the use of funds, for a period of up to three years after approval, to cover risk management activities for products approved after October 1, 2002. This change is highly important to the Managers, as improving drug and biological product safety is a goal shared by all.

The term "adjustment factor" is modified to eliminate obsolete provisions.

*Section 504. Authority to Assess and Use Drug Fees*

Subsection (a) of this section allows fees authorized by the Act to be assessed beginning on October 1, 2002. With respect to prescription drug establishment fees and prescription drug product fees, the subsection advances the date by which fees are payable to October 1 of each year.

Under the second Prescription Drug User Fee Act (PDUFA), prescription drug establishment and product fees, which represent two-thirds of PDUFA fees, were due January 31, four months into the fiscal year. This necessitated carrying forward funds from a previous year to sustain operations for the first four months of each new fiscal year. By advancing the date for annual fees to be paid to FDA, the necessity of carrying forward these large cash surpluses from year to year is eliminated. Also, by making this change effective for FY 2003, FDA will have access to revenue as early in FY 2003 as invoices can be issued and fees collected rather than having to wait until January 31 to collect funds. This is especially important for FDA operations in FY 2003 because the agency does not expect to have any appreciable carryover funds at the end of FY 2002.

Making the fee due and payable on October 1 necessitates other changes to the FFD&C Act that are executed in subsection (e) and (f) of this section.

This section sets forth a table containing the application, establishment, and product fee revenues, and total fee revenue, for fiscal years 2003 through 2007. The subsection further authorizes an increase in fee revenue amounts to fully fund the portion of additional costs attributable to the cost of the retirement of Federal personnel. This provision would go into effect, if, after the enactment of the Prescription Drug User Fee Amendments of 2002, legislation is enacted requiring the Secretary to fund additional costs of the retirement of Federal personnel.

This section also authorizes inflation adjustments, workload adjustments, and a final year adjustment. Under present law, annual inflation adjustments were based on the higher of the federal pay raise applicable for employees in the fiscal year for which the fees were set or the CPI for the previous year. In order to collect fees on October 1, FDA will have to set fees and issue invoices in August of each year, well before the pay-raise determination for the next fiscal year is made. For this reason the inflation adjustment factors have been changed to the Federal pay raise for employees in the Washington, D.C., area for the previous fiscal year, or the change in the CPI for the 12 month period ending June 30, whichever is higher. Both of these figures will be available in August when fees must be set. As has been the case in the past, these inflationary changes will continue to be cumulative and compounded.

Under the workload adjustment, annual revenue adjustments are made that reflect changes in review workload, after inflation adjustments. The workload adjustment is to be determined by the Secretary based on a weighted average of the changes in the total number of (1) human drug applications, (2) commercial investigational new drug applications, (3) efficacy supplements, and (4) manufacturing supplements. The subsection provides that the Secretary shall publish in the *Federal Register* the fees resulting from this adjustment and the supporting methodologies. Each of the 4 components used to develop the workload adjustment is a defined category of applications that FDA currently counts. Each component will be given a weighting factor that corresponds to its percent of FDA review workload.

The workload adjustment envisioned for each component has as its base the average number of applications of each particular type that FDA received over the five-year period of current law. It requires that a rolling average of submissions also be calculated each year for the latest five-year period that ends on June 30 before the end of each fiscal year beginning on or after October 1, 2002. The percent change in the latest five-year average, compared to the base year, is then multiplied by the weighting factor for that component. Then all four components of the workload adjuster are added together and the total percent that results is the workload adjuster that will be used to further adjust the inflation-adjusted statutory revenue levels each year after FY 2003. Use of five-year rolling averages in this process dampens the impact of revenue fluctuations—both up and down.

Under this section, the revenue adjuster will never result in lower revenues than the inflation-adjusted statutory revenue levels. Nonetheless, in years when fee-paying applications fall below projections, FDA will automatically experience a shortfall in revenues due to the shortfall in fee-paying applications. Further downward adjustment of the revenues would over-compensate for such a decline in workload and is not authorized under the subsection. This is a lesson learned from experience during 1998 through 2002. If such a model had been in place for the past five years, revenues during PDUFA II would have been much more predictable year to year rather than exhibiting the volatility FDA experienced.

Also under this section, FDA is allowed to make a one-time increase in fees in FY 2007, if necessary, to assure that the agency will have no less than three months of operating reserves on hand at the end of FY 2007, when this legislation will expire. This final year adjustment will allow the agency sufficient fees to operate for up to 3 months in FY 2008 if there is any delay in the reauthorization of PDUFA at the end of FY 2007. Further, delaying this payment from industry until FY 2007 minimizes the need for FDA to carry large balances over from year to year, reducing industry outlays until they are necessary to support operations.

Finally, this section provides that application, product, and establishment fees are to be established 60 days before the start of the fiscal year based on the revenue amounts previously established in this section.

Under subsection (d), the waiver or fee reduction for supplements filed under section 505(b)(1) of the FFD&C Act is eliminated.

In this section the word "assessed" in section 736(f) of the FFD&C Act has been changed to "retained." This change is part of a series of changes made to permit FDA to issue invoices and collect fees before an appropriation is actually made for the fiscal year. The change maintains the original intent of this and related provisions, however, by providing that the conditions originally specified in these sections must be fulfilled once all appropriations for the fiscal year, including any supplemental appropriations, are enacted. If the conditions are not fulfilled, FDA may not retain the fees it collects. Further, under this section, the word "collected" in section 736(g)(2)(A) of the FFD&C Act is changed to "retained." Once again, this change is part of a series of changes made to permit FDA to issue invoices and collect fees before an appropriation is actually made for the fiscal year. The change maintains the original intent of this and related provisions by asserting that the conditions originally specified in these sections must be fulfilled once all appropriations for the fiscal year, including any supplemental appropriations, are enacted.

This section also responds to the problems associated with FDA's inability under the FFD&C Act to collect and spend fees in any year that FDA fails to spend from appropriations as much as it spent in FY 1997, adjusted for inflation. Failing to meet this obligation by as little as one dollar causes FDA to lose the authority to collect application, product and establishment fees for a given fiscal year. The consequence of failing to meet this "trigger" would be catastrophic. Since the trigger is based on the amount FDA spends, the agency can never identify exactly how much it has actually spent until after the end of the fiscal year. As a result, FDA consistently overspends by a substantial amount to be certain that FDA expenditures do not fall below the trigger amount and thereby cause the agency to lose the authority to collect fees.

Modifications to section 736(g)(2)(B) are proposed to provide FDA a margin of error in its effort to meet this requirement of the law. This section is being modified so that if FDA's spending is within five percent of the amount required by this section of the Act, the requirement of this section is considered to be satisfied. If FDA under-spends by three percent or less, there are no consequences. If FDA under-spends by more than three percent but not more than five percent, FDA will be required to reduce collections in the fiscal year following the subsequent fiscal year by the amount in excess of three percent by which FDA under-spent from appropriations. The intent is to relieve FDA of the need to overspend from appropriations each year, as it has done consistently since 1993 to assure that this trigger is met. Spending from appropriations on the drug review process each year is still expected to be at or very close to the amount specified by this trigger, and may never be more than five percent below the trigger amount.

This section also authorizes appropriations for fiscal years 2003 through 2007 in amounts consistent with the total fee revenue amounts set forth in subsection (b).

*Section 505. Accountability and Annual Reports*

This section for the first time requires the agency to meet with interested public and private stakeholders when considering the reauthorization of this program before its expiration. The Managers believe that the agency will be in the best position to recognize what best serves the public health by meeting with representatives of consumer and patient advocacy groups, industry, the Congress, health care professionals, and academic experts prior to the next reauthorization of PDUFA. Further, the Managers believe that it is very important for the agency to make any recommendations to the Congress public, so this section requires that the FDA both publish the recommendations, as well as hold a public hearing at which time the agency can receive public feedback.

This section also requires an annual Performance Report and a Financial Report.

*Section 506. Reports of Postmarketing Studies*

Under this section, the Managers intend that in instances wherein a study subject to the reporting requirements of Section 130 is not completed by the original or otherwise negotiated deadline agreed upon by the sponsor and if the reasons for such failure to complete the study were not satisfactory to the Secretary, the Secretary shall so note on the agency website. The Managers intend that the Secretary would not find the delay or termination of a study unsatisfactory if the Secretary determined that the delay or termination occurred through no fault of the sponsor (such as ethical concerns, or the study is no longer needed).

This section also empowers the Secretary to require a sponsor of a study required under section 505(b)(2)(A) or sections 314.510 or 601.41 of Title 21, Code of Federal Regulations, to notify health care practitioners who prescribe such drugs or biological products of the sponsor's failure to complete the study, and the questions of clinical benefit and, where appropriate, questions of safety, that remain unanswered as a result of such failure. The Managers intend that this authority not be utilized in cases where, through no fault of the sponsor (such as ethical concerns, or the study is no longer needed), the study has been delayed or terminated.

*Section 507. Savings Clause*

This section authorizes user fees to be assessed and collected after October 1, 2002 for human drug applications and supplements accepted for filing prior to October 1, 2002. For example, in the event that application fees are owed but have not been collected prior to the expiration date for PDUFA II established by section 107 of the Food and Drug Administration Modernization Act (FDAMA), the section will allow these fees to be collected after October 1, 2002. The section further authorizes assessment and collection of product and establishment fees after October 1, 2002 that are owed but have not been collected.

*Section 508. Effective Date*

Section 508 provides that the Prescription Drug User Fee Amendments of 2002 shall take effect October 1, 2002.

*Section 509. Sunset Clause*

Section 509 provides that the amendments made by sections 503 (relating to definitions) and 504 (relating to the authority to assess and use drug fees) shall cease to be effective on October 1, 2007.

The section further provides that the amendments made by section 505 (relating to annual reports) shall cease to be effective 120 days after October 1, 2007. The additional 120 days will allow the prescription drug user fee reports for fiscal year 2007 to be prepared and submitted.

SUBTITLE B – ADDITIONAL AUTHORIZATIONS OF APPROPRIATIONS REGARDING FOOD AND DRUG ADMINISTRATION

*Section 521. Office of Drug Safety*

This section will help the FDA fulfill its vitally important role of ensuring drug safety. The Managers are highly supportive of the postmarket surveillance activities conducted by the Office of Drug Safety (ODS), and to that end other provisions in this legislation ensure for the first time that user fee monies will be available for postmarket purposes. This section complements those efforts by ensuring that not only will new user fee monies be available for this very important purpose, but so will new appropriated monies.

*Section 522. Division of Drug Marketing, Advertising, and Communications*

This section provides an increased authorization for the Division of Drug Marketing, Advertising, and Communications (DDMAC) within the Office of Medical Policy, Center for Drug Evaluation and Research at the FDA. DDMAC plays a vital role in ensuring that promotional drug material is not false or misleading, and they do so on a limited budget. The authorized amounts will better ensure that DDMAC can perform its mission.

*Section 523. Office of Generic Drugs*

This section provides an increased authorization for the Office of Generic Drugs (OGD) within the Center for Drug Evaluation and Research at the FDA. OGD is vitally important to ensuring that Americans have access to safe, effective generic drugs. This Office needs increased funding, however, due to the fact that it presently takes OGD nearly 18 months to review the typical ANDA. This section will lead to increased funding, so that these review times can be decreased without compromising health and safety.